

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION OPIATE  
LITIGATION

*This document relates to:*

Track One Cases

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO  
WALGREENS'S MOTION FOR SUMMARY JUDGMENT (Dkt. # 1764)**

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## INTRODUCTION

Walgreens's individual motion for summary judgment is limited to a single question: whether Plaintiffs were required to prove actual diversion as to the suspicious orders that Walgreens failed to properly flag, report, and/or halt in violation of Walgreens's regulatory duties.<sup>1</sup> As addressed in Plaintiffs' Consolidated Memorandum in Opposition to the Defendants' Motions for Summary Judgment on Causation ("PSJ2-Causation"), this granular level of proof is not required to satisfy the causation elements of Plaintiffs' claims, and Plaintiffs have provided evidence sufficient to demonstrate that Plaintiffs can adequately prove causation as to Plaintiffs' claims against Walgreens.

The arguments raised by Walgreens in its individual motion are red herrings: neither Plaintiffs' response to Discovery Ruling 12 nor the expert reports of Dr. McCann and Agent Rafalski were intended to provide evidence of pill-by-pill diversion but, instead, were intended to – and did provide – evidence of a baseline set of orders that should have been flagged and halted pending sufficient due diligence.

As discussed more fully in PSJ2-Causation, Walgreens's, and other Defendants', complete failure to meet their duties as distributors of controlled substances directly caused Plaintiffs' injuries. Walgreens admits the "opioid crisis" is caused by "misuse, abuse and addiction" that result from the "flow of opioids that fuel the epidemic."<sup>2</sup> Walgreens has also admitted that prescription opioid use has led to increased heroin abuse.<sup>3</sup> Plaintiffs' expert witnesses establish a direct chain of causation between Walgreens's conduct and the opioid crisis and increased heroin use that Walgreens admits

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<sup>1</sup> Walgreens also incorporates by reference, but does not provide further briefing in its individual motion on, arguments made in motions filed by the Pharmacy Distributors seeking dismissal based on statutes of limitations (See Pharmacy SOL MSJ, Dkt. # 1703); Causation (See Pharmacy Causation MSJ, Dkt. # 1774); Civil Conspiracy (Pharmacy Civil Conspiracy MSJ, Dkt. # 1716); and Preemption (See Pharmacy & Major Distr. Preemption MSJ, Dkt. # 1867). Plaintiffs' responses to those arguments are addressed in Plaintiffs' responses to those motions and are incorporated by reference herein.

<sup>2</sup> Exh. 1 - WAGMDL00007388.

<sup>3</sup> Exh. 2 - WAGMDL00035669 at WAGMDL00035676 (Walgreens acknowledges the proven link between "Prescription Opioids and Heroin", noting that "[n]early 80% of Americans using Heroin reported misusing opioids first" and that "[i]ndividuals who misuse prescription opioid pain pills are forty times more likely to abuse heroin.").

exists. Mr. Rafalski and Dr. McCann, who illustrate the startlingly number of suspicious orders that were shipped without appropriate due diligence, show that Defendants, including Walgreens, did not have sufficient controls to prevent diversion, thereby predictably leading to a large quantity of opioids entering the illicit market.<sup>4</sup> Professor Gruber establishes a direct, causal relationship between shipments of prescription opioids by Walgreens and other Defendants and the misuse and mortality from prescription opioids.<sup>5</sup> Professor Cutler sets forth the effect of prescription opioid shipments on the harms that resulted in costs to the counties.<sup>6</sup> Professor McGuire concludes that a public nuisance has resulted from the shipment of prescription opioid products into the Bellwether communities.<sup>7</sup> The admissible testimony from these witnesses is independently sufficient to meet Plaintiffs' causation burden.

Additionally, evidence obtained by Plaintiffs in this litigation demonstrates the causal link between Walgreens's excess supply of opioids to Summit and Cuyahoga counties and the resulting opioid epidemic, and further reveals the connection between the 2012 regulatory action and findings against Walgreens and Plaintiffs' claims in Summit and Cuyahoga Counties.

## **I. STATEMENT OF FACTS**

Between 1996 and 2014, Walgreens shipped approximately 133,938,529 dosage units of opioids into Summit and Cuyahoga Counties.<sup>8</sup> Of those, at least 125,133,525 dosage units were shipped in fulfillment of orders that, under the Controlled Substances Act ("CSA"), were "suspicious" and should never have been shipped.<sup>9</sup> Walgreens failed to implement an effective

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<sup>4</sup> See PSJ2-Causation; See also Plaintiffs' Opposition to Defendants' Motions to Exclude the Opinions and Testimony of Dr. Craig McCann and James Rafalski ("PD4 – Rafalski/McCann").

<sup>5</sup> Report of Jonathan Gruber, PhD, Dkt. # 2000-6 at 8 ¶16.

<sup>6</sup> Report of David Cutler, PhD, Dkt. # 2000-4 at Appendix III.J.

<sup>7</sup> Report of Thomas McGuire, PhD, Dkt. # 2000-18 at 7 ¶14.

<sup>8</sup> Report of Craig McCann, PhD, CFA, Dkt. # 2000-14 at Appendix 10 at 226 and 856 of 1260.

<sup>9</sup> *Id.* See also McCann Rep. Dkt. # 2000-14; Report of James Rafalski, Dkt. # 2000-22.

suspicious order monitoring program required to meet its obligations under the CSA.<sup>10</sup> Walgreens made little effort to properly identify suspicious orders, failed to flag orders and report them to the DEA, failed to halt suspicious orders pending due diligence, and instead focused on keeping the flow of drugs into Summit and Cuyahoga Counties.

Walgreens knew that its Suspicious Order Monitoring (“SOM”) system did not comply with its CSA obligations. In May 2006, the DEA sent Walgreens a Letter of Admonition citing Walgreens for controlled substances violations at its Perrysburg, Ohio Distribution Center. Specifically, the DEA informed Walgreens that the “formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient,”<sup>11</sup> and “inadequate.” The DEA reminded Walgreens that its suspicious ordering “formula should be based on (size, pattern, frequency).”<sup>12</sup>

After receiving the Letter of Admonishment, Walgreens decided to utilize a “three times” formula based on Appendix E-3 of the Chemical Handler’s Manual to generate and send the DEA a monthly report of “Suspicious Control Drug Orders” that Walgreens had filled for its stores.<sup>13</sup> Walgreens sent these post-shipment “Suspicious Control Drug Orders” reports to the DEA from 2007 through 2012. Despite the orders being flagged in the reports for being “suspicious” based on volume alone, Walgreens did not halt these orders or perform any due diligence on them before shipment.<sup>14</sup> Walgreens did not perform the size, pattern, and frequency analysis prescribed by the DEA, but merely used this “three times” formula to list the orders on an after the fact report and then continued shipping.

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<sup>10</sup> Walgreens’s significant breaches of its duties under the CSA, and much of the evidence developed in support thereof, is set out in detail in Plaintiffs’ Memorandum of Law in Support of Motion for Partial Summary Adjudication that Defendants Did Not Comply with Their Duties Under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them, Dkt. # 1799 (“FCSA Noncompliance”); Rafalski Rep., Dkt. # 2000-22 at 114–187; and Report of Seth Whitelaw, JD, LLM, Dkt. # 2000-26 at 183-208.

<sup>11</sup> Exh. 3 - WAGMDL00709510.

<sup>12</sup> Exh. 62 -WAGMDL00709508 (DEA Audit Preliminary Response 03-06-06).

<sup>13</sup> Exh. 4 - WAGMDL00400357.

<sup>14</sup> See Exh. 5 - Errata to Eric Bratton 30(b)(6) Deposition at 5.

Walgreens knew that this type of post-shipment “excessive purchase report” did not satisfy the requirements of 21 C.F.R. § 1301.74(b).<sup>15</sup>

In September 2007, three Walgreens’s senior employees attended a conference at which the DEA reminded registrants that the CSA “requirement is to report suspicious orders, not suspicious sales after the fact,” and advised the audience not to “confuse suspicious order report with an excessive purchase report. They are two different things.”<sup>16</sup>

In November 2012, Walgreens’s Divisional Vice President of Pharmacy Services reported to Walgreens’s President of Pharmacy, Health and Wellness, Kermit Crawford, his notes from a meeting with the DEA regarding reporting of suspicious orders, which included the notation, “If suspicious - you don't ship.”<sup>17</sup>

Despite knowing for approximately 20 years that its SOM policies were inadequate and violated the law, being admonished by the DEA, and receiving specific instruction that the post-shipment excessive purchase reports did not satisfy its duties, Walgreens still did not institute a SOM

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<sup>15</sup> As early as April 27, 1984, the DEA reminded the National Wholesale Druggists’ Association that “an after-the-fact computer printout of sales data does not relieve a registrant of its responsibility to report excessive or suspicious orders when discovered.” Exh. 6 - US-DEA-00026139 at US-DEA-00026148. On May 16, 1984, the DEA again sent the National Wholesale Druggists’ Association the same reminder. Exh. 6 - US-DEA-00026139 at US-DEA-00026150.

In April 1987, manufacturers and wholesalers of controlled substances were again reminded by the DEA that they needed to design and operate a system to disclose suspicious orders. Exh. 7 - US-DEA-00025656 at US-DEA-00025659. Manufacturers and wholesalers of controlled substances were also reminded that they would bear responsibility for reporting a suspicious order and then shipping it. *Id.*

On November 4, 1988, Walgreens met with the DEA and was again reminded, “The submission of a monthly printout of after-the-fact sales does not relieve the registrant of the responsibility of reporting excessive or suspicious orders. These regulations require that a registrant maintain a system to detect excessive ‘orders’ rather than sales of controlled substances.” Exh. 8 - US-DEA-00025683.

On June 21, 1993, the National Wholesale Druggists’ Association reminded registrants that suspicious order submissions “of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting these single excessive or suspicious orders.” Exh. 6 - WAGMDL00400357 at US-DEA-00026146.

In DEA interviews Walgreens’s Corporate Counsel stated “that DEA had informed Walgreens that this algorithm reporting system was outdated and that Walgreens needed to establish their own system for reporting suspicious orders.” Exh. 9 – WAGMDL00490963 at WAGMDL00387688.

<sup>16</sup> Exh. 10 - Acquired\_Actavis\_00441354 at 441355; Exh. 11 - CAH\_MDL\_PRIORPROD\_DEA07\_01185382 at CAH\_MDL\_PRIORPROD\_DEA07\_01185404-5 (attended by Dwayne Pinon, Senior Attorney; James Van Overbake, Auditor; and Irene Lerin, Audit Manager); Exh. 12 - CAH\_MDL\_PRIORPROD\_DEA12\_00011059; Exh. 13 - HDS\_MDL\_00002032 at 2040.

<sup>17</sup> Exh. 14 - WAGMDL00658246 at WAGMDL00658247.

program.<sup>18</sup> Walgreens admits that the DEA instructed Walgreens to “stop what was considered suspicious drug shipments to any of our stores.”<sup>19</sup> However, Walgreens continued to ship all flagged orders without due diligence review and continued to send a post-shipment report to the DEA regarding all orders triggered by the Appendix E-3 Chemical Handler’s test. This remained Walgreens’s practice until the end of 2012, even as Walgreens slow played its development of a more robust SOM program.<sup>20</sup>

It was not until March 2008, in response to three of Cardinal Health’s Distribution Centers being shut down by the DEA for suspicious drug ordering violations, that Walgreens “beg[an] creating” a SOM program, but Walgreens took more than four years to fully implement the program.<sup>21</sup> In December 2008, Walgreens conducted an internal audit of its Perrysburg, OH Distribution Center. That audit found that significant issues related to Walgreens’s suspicious controlled drug order processing and reporting system were still open from DEA’s May 2006 inspection, and that these issues *existed nationwide at all Walgreens distribution centers*.<sup>22</sup>

While Walgreens made changes and refinements to its program, at no time during this period did Walgreens investigate all orders flagged as suspicious before shipping them. The program did not halt suspicious orders for due diligence evaluation or report the orders as suspicious, but rather focused on cutting outsized orders to an (adjustable and ever increasing) threshold amount and then

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<sup>18</sup> Exh. 15 - WAGMDL00757193 (“internal controls that ensure compliance with DEA regulations ... pertain[ing] to all company DCs ... should be addressed to void potential DEA sanctions”, noting that these issues had been pending and “un-remediated” since audits in 2005 and 2006, and included “suspicious controlled drug order processing and reporting” and “lack of formalized CII controlled substance policies and procedures.”); *See also* Exh. 9 WAGMDL00490963 at WAGMDL00709508 (“suspicious ordering report is inadequate”); Exh. 3 - WAGMDL00709510 (“formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient”).

<sup>19</sup> Exh. 16 - WAGMDL00660331.

<sup>20</sup> *See* Exh. 17 - WAGMDL00625263 at WAGMCL00625264 and 00625265 (PowerPoint presentation identifying five phases to Walgreens’s “Ongoing Controlled Substance Order Review Logic” spanning from 2009 until 2012).

<sup>21</sup> Exh. 18 - WAGMDL00659801 at WAGMDL00659818; Exh. 19 - WAGMDL00709395.

<sup>22</sup> Exh. 15 - WAGMDL00757193.



filling them.<sup>23</sup> The DEA has clearly stated that cutting orders that exceed a threshold to a lower volume and then shipping them without review is a violation of a distributor's duties under the CSA.<sup>24</sup>

Not only did Walgreens's SOM program not halt or report the orders its SOM program flagged as suspicious, but there were other loopholes that limited the program's effectiveness, including: (1) allowing stores to place orders to an outside vendor; (2) failing to include orders to outside distributors in its analysis; (3) allowing stores to obtain over-limit opioids from another Walgreens-owned store when they hit Walgreens's threshold ("interstoring")<sup>25</sup>; (4) permitting stores to order outside of the SOM limits through a PDQ ("pretty darn quick") system<sup>26</sup>, and (5) routinely granting threshold increases with nominal due diligence.<sup>27</sup>

In April 2012, the DEA served a Subpoena and a Warrant of Inspection on one of Walgreens's three Schedule 2 controlled substance distribution centers, the Jupiter, Florida Distribution Center ("Jupiter DC"), seeking all controlled substance SOPs, communications about controlled substances, customer due diligence files for 14 Walgreens stores, and all records related to distribution of controlled substances.<sup>28</sup>

After the DEA instituted its regulatory investigation, Walgreens engaged in meetings with the DEA about Walgreens's "Controlled Substance Anti-Diversion and Compliance Program" in an effort to "cooperate and avoid litigation," and represented to the DEA that it was making "new

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<sup>23</sup> Exh. 20 - WAGMDL00624527; Exh. 21 - WAGMDL00667936 at WAGMDL00667938 and WAGMDL00667940; Exh. 22 - WAGMDL00658227; *See also* FCSA Noncompliance, Dkt. # 1799; Rafalski Rep., Dkt. # 2000-22 at 114-187; and Whitelaw Rep., Dkt. # 2000-26 at 183-208.

<sup>24</sup> Exh. 14 - WAGMDL00658246 at WAGMDL00658247.

<sup>25</sup> *See* Natasha Polster Dep. (01/23/2019), Dkt. # 1969-10 at 250:1-253:7 and 257:14-258:2.

<sup>26</sup> Exh. 23 - WAGMDL00705321.

<sup>27</sup> Exh. 24 - WAGMDL00010887 (showing approval rate for threshold requests at 95%+ for FY 2014 and 2015).

<sup>28</sup> Exh. 25 - WAGMDL00777158; Exh. 26 CAH\_MDL2804\_01431069 at 01431074.

changes” to “enhance” its SOMS program.<sup>29</sup> Internally, Walgreens stated that it only enhanced its SOMS program “in an effort to convince DEA that the proposed penalty is excessive...”<sup>30</sup>

As a result of the DEA investigation, Walgreens formed the Pharmaceutical Integrity (“RX Integrity”) group in 2012 to purportedly address Walgreens’s SOM noncompliance. However, the group viewed its real role as protecting the Distribution Centers (“DCs”) and stores from losing their DEA licenses.<sup>31</sup> The effort was only for show. Walgreens never provided RX Integrity with the necessary resources to perform adequate due diligence on the overwhelming number of orders identified by Walgreens’s SOM algorithm for Walgreens’s 5,000 plus stores.<sup>32</sup> In December 2012, Walgreens’s “updated” SOM program resulted in 14,000 flagged orders that required due diligence review.<sup>33</sup> At the time these 14,000 orders were flagged, Walgreens’s RX Integrity department consisted of fewer than 5 people, and at its height, it only had eleven members.<sup>34</sup> On January 4, 2013, a Walgreens employee raised concern that the suspicious orders they were able to investigate were already a week old and most cases were already shipped.<sup>35</sup> Instead of sufficiently staffing the SOM program, Walgreens noted that it had the ability to control its due diligence workload by simply increasing stores’ ceiling levels, thereby reducing the number of orders that would breach that ceiling and result in a flag.<sup>36</sup>

After reviewing the materials provided by Walgreens in response to the April 2012 subpoenas, and meeting with Walgreens on September 13, 2012, the DEA issued an Order to Show Cause (OTSC) and Immediate Suspension of Registration (ISO) to Walgreens.<sup>37</sup> The basis for the OTSC and ISO was Walgreens’s extraordinary distribution of opioids and other related regulatory

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<sup>29</sup> Exh. 18 - WAGMDL00659801 at WAGMDL00659802.

<sup>30</sup> Exh. 27 - WAGMDL00659270.

<sup>31</sup> See Exh. 29 - WAGMDL00101723; Exh. 30 -WAGMDL00060486.

<sup>32</sup> See Polster Dep., Dkt # 1969-10 at 133:10-13.

<sup>33</sup> See Exh. 27 - WAGMDL00659270.

<sup>34</sup> See Polster Dep., Dkt # 1969-10 at 240:3-15.

<sup>35</sup> Exh. 28 - WAGMDL00414048.

<sup>36</sup> *Id.*

<sup>37</sup> Exh. 9 - WAGMDL00490963 at WAGMDL00387654.

violations. The DEA found that Walgreens's continued operation of the Jupiter DC constituted "an imminent danger to the public health and safety" and ordered that Jupiter DC's controlled substance vault be sealed.<sup>38</sup> The DEA further found that Walgreens's Jupiter DC failed to comply with DEA regulations that required it to report to the DEA suspicious drug orders that Walgreens received from its retail pharmacies,<sup>39</sup> resulting in at least tens of thousands of violations, particularly concerning massive volumes of prescription opiates.<sup>40</sup> The DEA stated: "Walgreens has failed to maintain an adequate suspicious order reporting system and as a result, has ignored readily identifiable orders and ordering patterns that, based on the information available throughout the Walgreens Corporation, should have been obvious signs of diversion occurring at Respondent's customer pharmacies."<sup>41</sup>

Walgreens admits that the SOM systems and procedures at all of its DCs were the same, including those at the facilities that continued shipping opioids into Summit and Cuyahoga Counties.<sup>42</sup> Accordingly, it is not surprising that, in February 2013, the DEA issued similar Subpoenas and Warrant of Inspection on the Perrysburg DC in Ohio to those issued to the Jupiter DC in Florida.<sup>43</sup> Walgreens employees made plans in preparation for the Perrysburg DC being "shut down" by the DEA, like the Jupiter DC.<sup>44</sup> Both the Florida and Ohio DCs distributed prescription opioids into CT1.<sup>45</sup>

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<sup>38</sup> See Exh. 9 - WAGMDL00490963 at WAGMDL00387654 (Letter from Michele Leonhart to Walgreen Company, *Order to Show Cause and Immediate Suspension of Registration* (Sept. 13, 2012), ["Jupiter Show Cause Order"]).

<sup>39</sup> *Id.*

<sup>40</sup> *Id.* at WAGMDL00387676;

<sup>41</sup> *Id.* at WAGMDL00387657.

<sup>42</sup> Eric Stahmann Dep. (10/16/18), Dkt. # 1971-2 at 94-96 (Suspicious Control Drug Report process used for all DCs "nationwide."); Deborah Bish Dep., Dkt. # 1959-2 at 34-37 (Perrysburg, Ohio DC employees and Woodland, CA DC employees were trained on Schedule II distribution policies and procedures by Jupiter DC, which were uniform across the distribution centers); Exh. 31 - Tomson George Dep. (01/14/19) at 91-97 (The same SOM related programs regarding dispensing were in place in all fifty states, including Florida and Ohio).

<sup>43</sup> Exh. 32 - WAGMDL00493697; Exh. 33 - WAGMDL00493694.

<sup>44</sup> Exh. 34 - WAGMDL00477975; Exh. 35 - WAGMDL00358471.

<sup>45</sup> See Rafalski Rep., Dkt. # 2000-22 at 114 (The Jupiter DC distributed prescription opioids into CT1 from 2002-2007, and the Perrysburg, Ohio DC distributed prescription opioids into CT1 from 2003-2013).

Within weeks of receiving the six subpoenas and warrant, Walgreens decided to “discontinue distribution of controlled substances from the Perrysburg facility” in order to “eliminate any immediate need for further DEA administrative action” regarding the Perrysburg facility.<sup>46</sup>

On June 11, 2013, Walgreens entered into a Settlement and Memorandum of Agreement (“MOA”) with the DEA to resolve outstanding allegations involving the Walgreens DCs and pending actions concerning six Walgreens retail pharmacies located in Florida. Walgreens agreed to pay \$80 million in civil penalties, the largest settlement in DEA history at that time, to resolve the DEA’s claims that Walgreens negligently allowed controlled substances, including oxycodone and other prescription painkillers, to be diverted into the black market.<sup>47</sup> In addition to the \$80 million civil penalty, Walgreens agreed to surrender its Jupiter DC’s registration to distribute, and certain chain pharmacies’ registration to dispense, controlled substances listed in Schedules II – V for two years from issuance of the Jupiter ISO, ending in 2014. As part of the MOA, Walgreens admitted that its “suspicious order reporting for distribution to certain pharmacies did not meet the standards identified by DEA in three letters from DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including Walgreens, on September 27, 2006, February 7, 2007 and December 27, 2007.”<sup>48</sup>

The evidence revealed by Walgreens’s production in this litigation shows that the regulatory issues and red flags which led to the Jupiter DC ISO extended throughout Walgreens’s nationwide operations, including in Ohio. For example, in 2012, when Anda analyzed Walgreens’s controlled substances sales by state, it observed: “Although we thought FL/GA stores might be more “questionable” than other states, the data has actually shows that this is not the case .... On a

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<sup>46</sup> Exh. 36 - WAGMDL00674280. Due to the shutdown of Walgreens’ Perrysburg DC in Ohio, Kermit Crawford, Walgreens’s former President of Pharmacy, Health and Wellness, called upon Cardinal Health for assistance to switch distribution of opioids from the Perrysburg DC to Cardinal Health DCs for shipment. *See* Exh. 37 - WAGMDL00705303; Exh. 38 - WAGMDL00682159. Crawford referred to this process as the “lift and shift.” *See* Exh. 37 - WAGMDL00705303.

<sup>47</sup> *See* Exh. 9 - WAGMDL00490963.

<sup>48</sup> *Id.*

national level, 21% of Rx's and 24% of pill count are Controlled Substances vs. Non-Controls .... FL/GA stores are not necessarily "abnormal" .... There are other states that have somewhat comparable questionable store percentages ...." Also, attached was a chart showing that 192 out of 255 Ohio Stores should be red flagged for the high number of controlled substances, including oxycodone, being dispensed.<sup>49</sup>

This information was not a surprise to Walgreens, which knew that its failure to institute effective controls against diversion was universal, as noted in its 2008 Internal Audit. Walgreens further had complete visibility into all opioid prescription data related to its stores, and internally touted its ability to conduct sophisticated "[d]ata mining... across [its] retail pharmacies to determine the maximum amount that a pharmacy should be allowed to receive..." though it failed to appropriately incorporate this data into its SOM program to prevent the excessive flood of opioids into Ohio.<sup>50</sup>

Not only did both the Perrysburg, Ohio DC fail to employ effective controls against diversion, just like the Jupiter DC, but the evidence produced in this litigation shows that Walgreens knew the flood of pills into Florida were being diverted into Ohio. For example, a DEA presentation in Walgreens's production specifically ties "Florida Migration" to Ohio, stating that the "[v]ast majority of 'patients' visiting Florida 'pain clinics' come from out of state:... [including] Ohio."<sup>51</sup> Though the 2012 ISO primarily focused on examples of bad conduct in Florida, Walgreens internal presentations to educate its "Market Leadership" on the 2012 Jupiter, Florida DC ISO state, "The key to note is that this isn't just a Florida problem."<sup>52</sup>

Walgreens knew that the DEA was conducting a "crackdown on Florida pharmacies where the market is notorious for illicit prescription painkillers" and that Walgreens's own pharmacies

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<sup>49</sup> Exh. 39 - WAGMDL00774715; Exh. 40 - WAGMDL00774717; Exh. 41 - WAGMDL00774718.

<sup>50</sup> Exh. 42 - WAGMDL00757776.

<sup>51</sup> Exh. 43 - WAGMDL00289068 at WAGMDL00289153.

<sup>52</sup> Exh. 44 - WAGMDL00049752 at WAGMDL00049759 (*See* speaker notes).

accounted for 53 of the top 100 retail sellers of oxycodone in Florida.<sup>53</sup> Walgreens also knew these pills being sold into the “epicenter[s] of [the] notorious well-documented epidemic of prescription drug abuse... were migrating to other states,” and that many “prescriptions [were] not for a legitimate medical purpose.”<sup>54</sup> Walgreens also received presentations highlighting an Ohio drug ring’s trips to Florida to get pills, and significant volumes of opioid prescriptions from Florida doctors for Ohio and Kentucky patients being filled in Ohio.<sup>55</sup>

Walgreens’s documents admit the link between the volume of opioids shipped to stores and diversion. When Walgreens created the RX Integrity Department to try to convince the DEA to lower the fines against Walgreens, Walgreens stated that the purpose of the department was to “play a greater role in the Opioid Narcotic Epidemic ... [by] ensuring safety, compliance, and security of the ordering and dispensing of controlled substances” including by “investigat[ing] and report[ing] suspicious orders externally to the DEA ... and other agencies” and by “utiliz[ing] the Controlled Substance Order Monitoring System (CSOM) to manage the amount of controlled substance[s]...shipped to the stores.”<sup>56</sup> A Walgreens VP of Pharmacy Retail Operations and Planning testified that the purpose of distributors submitting suspicious orders to the DEA “was to detect diversion, misuse.”<sup>57</sup>

Walgreens admits the “opioid crisis” is caused by “misuse, abuse and addiction” that result from the “flow of opioids that fuel the epidemic.”<sup>58</sup> Walgreens’s documents link the “[i]ncreases in death rates from overdose [as] related to increased availability of opioid prescriptions,” noting that “[t]hose who receive higher doses of opioids are at greater risk for overdose,” but also acknowledges

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<sup>53</sup> Exh. 45 - WAGMDL00119539.

<sup>54</sup> Stahmann Dep. Dkt. # 1971-2 at 207; see also Exh. 46 – Sean Barnes Dep. (10/22/18) at 127:4-12; 255:7-17.

<sup>55</sup> Exh. 47 - WAGMDL00441397 at WAGMDL041412 - 419.

<sup>56</sup> Exh. 48 - WAGMDL00303029.

<sup>57</sup> Eric Swords Dep. (12/21/18), Dkt. # 1971-8 at 203:18-204:4; 204:20-23.

<sup>58</sup> Exh. 1 - WAGMDL00007388.

that the opioid abuse epidemic “can be prevented and treated.”<sup>59</sup> Walgreens admits its role in the opioid epidemic, stating it has the “ability – and [] critical responsibility – to fight the opioid crisis” as the “nation’s largest pharmacy chain” in a time when “[a]ddiction to prescription painkillers, heroin, and other opioids has surged, with opioid overdoses quadrupling in this decade” and “drug overdose deaths – the majority from prescription and illicit opioids” resulting in “more fatalities than from motor vehicle crashes and gun homicides combined.”<sup>60</sup> Additionally, Walgreens admitted there was a “troubling trend in the United States” in 2010 when prescription drugs surpassed motor vehicle fatalities and other drugs and poisons as the leading cause of accidental death.<sup>61</sup>

Walgreens’s documents also acknowledge the proven link between “Prescription Opioids and Heroin”, noting that “[n]early 80% of Americans using Heroin reported misusing opioids first” and that “[i]ndividuals who misuse prescription opioid pain pills are forty times more likely to abuse heroin.”<sup>62</sup>

Walgreens’s presentations estimate that the opioid epidemic costs “\$55.7 billion nationally” including “\$25 billion in healthcare costs” and “5.1 billion in criminal justice costs.”<sup>63</sup> Walgreens further admits that the “[a]verage annual healthcare costs for those that abuse opioids are about 8 times higher than those that do not abuse.”<sup>64</sup>

In 2014, Walgreens ceased self-distribution of opioids into CT1;<sup>65</sup> however, as further detailed in Plaintiffs’ Opposition to the Pharmacy Distributors Conspiracy Motion, Walgreens’s malfeasance did not end there. When it ceased self-distribution, Walgreens entered into an agreement with AmerisourceBergen under which AmerisourceBergen became Walgreens’s exclusive

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<sup>59</sup> Exh. 49 - WAGMDL00608995 at WAGMDL00608999.

<sup>60</sup> Exh. 1.

<sup>61</sup> Exh. 50 - WAGMDL00114602 at WAGMDL00114613.

<sup>62</sup> Exh. 2 - WAGMDL00035669 at WAGMDL00035676.

<sup>63</sup> *Id.*

<sup>64</sup> Exh. 49 - WAGMDL00608995 at WAGMDL00608999.

<sup>65</sup> *See, e.g.*, Exh. 51 - WAGMDL00095936; Exh. 52 - WAGMDL00095937; Rafalski Rep., Dkt. # 2000-2 at 132.

controlled substance distributor.<sup>66</sup> As part of this “partnership”, Walgreens ultimately acquired more than 26% of AmerisourceBergen stock and is now considered a related party under SEC rules.<sup>67</sup> Since joining forces with Defendant AmerisourceBergen, Walgreens and AmerisourceBergen have worked together to ensure continued supply of opioids in Walgreens’s stores and to avoid reporting to the DEA suspicious orders made by Walgreens pharmacies. For example, during the process of transitioning Walgreens’s distribution to AmerisourceBergen, one AmerisourceBergen employee stated: “I’m trying to think of everything we can do to prevent having a bunch of orders reported to DEA and held.”<sup>68</sup> Further, despite DEA guidance that “a suspicious order placed by a customer pharmacy is made no less suspicious by application of a system designed to reduce or eliminate such orders prior to shipping”,<sup>69</sup> AmerisourceBergen and Walgreens agreed to set up a system with the “goal” to have Walgreens “police their own orders and block any order to ABC that would exceed ABC’s threshold thus triggering a suspicious order being sent to DEA from ABC.”<sup>70</sup> When this system proved less than fully functional, and orders “outside the expected usage” were made by Walgreens, AmerisourceBergen and Walgreens set up meetings to address the concern.<sup>71</sup> Potential solutions to the concern were adjusting thresholds or using “soft blocking”.

Although AmerisourceBergen’s stated policy was to not divulge thresholds<sup>72</sup>, and contrary to guidance given to AmerisourceBergen by the DEA,<sup>73</sup> AmerisourceBergen provided Walgreens with

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<sup>66</sup> Exh. 60 - WAGMDL00000417 (Walgreen AmerisourceBergen Pharmaceutical Purchase and Distribution Agreement).

<sup>67</sup> 2016 AmerisourceBergen Annual Report, p. 72, found at <http://investor.amerisourcebergen.com/financial-information/sec-filings>.

<sup>68</sup> Exh. 53 - ABDCMDL00280818.

<sup>69</sup> Exh. 9 - WAGMDL00490963 at WAGMDL00387659; see also *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206, 217-218 (D.C. Cir. 2017) (“While deleting or editing orders may have limited the amount of oxycodone flowing to Masters’ customers, that practice subverted the Reporting Requirement. The law requires registered suppliers like Masters to alert DEA when their retail-pharmacy customers *attempt* to obtain unusual amounts of a controlled substance, because such attempts are powerful evidence that the pharmacies are operating illegally.”).

<sup>70</sup> Exh. 54 - ABDCMDL00277369.

<sup>71</sup> Exh. 55 - ABDCMDL00278991.

<sup>72</sup> Exh. 56 - Edward Hazewski Dep. (10/25/18) at 121:22-122:2

<sup>73</sup> Exh. 57 - ABDCMDL00285348.



the threshold limits set in AmerisourceBergen's order monitoring program.<sup>74</sup> AmerisourceBergen also provided Walgreens with weekly statistics related to AmerisourceBergen's order monitoring, which showed individual Walgreens stores that exceeded the parameters of ABC's order monitoring program.<sup>75</sup> Generally, AmerisourceBergen would not take action on Walgreens orders that exceeded AmerisourceBergen's thresholds without talking to Walgreens.<sup>76</sup> Accordingly, Walgreens has continued to work with the other Defendants to ensure the supply of opioids, including into CT1, was not disrupted.

## II. DEFENDANTS FAIL TO MEET THEIR BURDEN OF PROVING NO CAUSATIVE LINK

The moving party has the burden of showing that no genuine dispute exists as to any material fact. *Hickle v. Am. Multi-Cinema, Inc.*, 927 F.3d 945, 951 (6th Cir. 2019). Summary judgment must be denied "if a reasonable jury could return a verdict for the nonmoving party[.]" *Kolesar v. Allstate Ins. Co.*, No. 1:19 CV 35, 2019 WL 2996047, at \*2 (N.D. Ohio July 9, 2019) (Polster, J.) (citing *Baynes v. Cleland*, 799 F.3d 600, 606 (6th Cir. 2015)). In making this determination, "the court must view the facts and any inferences reasonably drawn from them in the light most favorable to the nonmoving party." *Id.* (citing same). Courts do not weigh the evidence or otherwise engage in "jury functions" in deciding a motion for summary judgment; "[i]f there remains any material factual disagreement as to a particular legal claim, that claim must be submitted to a jury." *Hickle*, 927 F.3d at 951 (citing *Bobo v. United Parcel Serv., Inc.*, 665 F.3d 741, 748 (6th Cir. 2012)). As shown herein, Walgreens has failed to show the absence of genuine disputes of material facts with regard to causation.

Both Congress and the DEA have found that the failure to monitor, report, and halt the shipment of suspicious orders of opioids causes both diversion and the types of harms that Plaintiffs

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<sup>74</sup> Exh. 58 - ABDCMDL00282490; Exh. 56 - Hazewski Dep. at 123:17-126:19.

<sup>75</sup> Exh. 59 - Elizabeth Garcia Dep. (12/14/18) at 280:23-282:1.

<sup>76</sup> *Id.* at 299:19-303:11.

and their communities have suffered.<sup>77</sup> These harms are precisely the injuries that one would expect Defendants' misconduct to cause, which in itself creates a triable issue of fact as to causation.<sup>78</sup> The sufficiency of Plaintiffs' causation showing is bolstered by their experts' testimony.<sup>79</sup> Further, Plaintiffs properly rely on circumstantial evidence (such as timing),<sup>80</sup> Defendants' admissions,<sup>81</sup> and aggregate proof models to create a triable issue as causation.<sup>82</sup>

### III. PLAINTIFFS' DISCOVERY RESPONSES AND EXPERT TESTIMONY SUPPORT THE CAUSATION ELEMENTS OF PLAINTIFFS' CLAIMS

#### A. Plaintiffs' Responses to Discovery Ruling No. 12 Comply with the Court's Order and Support Plaintiffs' Claims Against Walgreens

Walgreens misrepresents the requirements of Discovery Ruling 12 ("DR-12"), with which Plaintiffs fully complied. DR-12 required Plaintiffs to: "identify 10 Suspicious Orders for Prescription Opioids that you contend were shipped to Your geographic area during the Relevant Time Period" and to "explain in detail all criteria you used to identify these Suspicious Orders, including whether and why you contend (i) any due diligence actually conducted was insufficient, and (ii) the order was so suspicious that there was no amount of due diligence that could have removed every basis to suspect the customer was engaged in diversion." *See* DR-12 (Dkt. # 1174) at p. 14.

The Court later amended and clarified DR-12 to specify that, for each defendant, the Plaintiffs should submit 10 Suspicious Orders for Summit and 10 Suspicious Orders for Cuyahoga

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<sup>77</sup> *See* PSJ2 Causation.

<sup>78</sup> *Empire Title Services, Inc. v. Fifth Third Mortg. Co.*, 2013 WL 1337629, \*9 (N.D. Ohio 2013); *See also, Brown v. Wal-Mart Stores, Inc.*, 198 F.3d 244 (6th Cir. 1999) (allowing jury to infer causation where harm incurred was expected consequence).

<sup>79</sup> *See* PSJ2 Causation; *See also, Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 267 (6th Cir. 2001) (expert testimony can establish factual disputes at summary judgment stage by providing provide basis from which causal sequence may be inferred).

<sup>80</sup> *See* PSJ2 Causation; *See also, Hardyman* 243 F.3d 255 at 269;

<sup>81</sup> *See* PSJ2 Causation; *See also, In re Meridia Prod. Liab. Litig.*, 328 F. Supp. 2d 791, 810 (N.D. Ohio 2004), *aff'd sub nom. Meridia Prod. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861 (6th Cir. 2006).

<sup>82</sup> *See* PSJ2 Causation. *See also, In re Neurontin Mktg. & Sales Practices Litig. (Harden)*, 712 F.3d 60, 68 (1st Cir. 2013); *In re Neurontin Mktg. & Sales Practices Litig. (Aetna)*, 712 F.3d 51, 58 (1st Cir. 2013).

from a “variety of recipient pharmacies and dates.” *See* January 18, 2019 email ruling from Special Master Cohen.

In compliance with the Amended and Clarified Order, Plaintiffs identified 10 orders from 10 different Walgreens pharmacies in Summit County and 10 orders from 10 different Walgreens pharmacies in Cuyahoga County. For each order, Plaintiffs identified the reason the orders should have been flagged as suspicious and specified whether there was an absence of any evidence of due diligence for the order, or whether, if there was due diligence, the order was so suspicious that no amount of due diligence could have dispelled the suspicion. *See* Plaintiffs’ Response to the Amended and Clarified DR-12 Supplemental Interrogatory Issues to Plaintiffs at p. 5; Exh. A, p. 12; and Exh. B, p. 11. For each order identified, Plaintiffs stated that no due diligence was evident from Walgreens’s production. *Id.* at Exh. A, p. 12; and Exh. B, p. 11. Each order identified by Plaintiffs was flagged by, *inter alia*, the “common sense” test endorsed by *Masters*. *Id.* *See also Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.D.C. 2017) (holding orders identified by the test were “unusual,” and not “normal”, and thus could not legally be shipped without sufficient due diligence).

Significantly, DR-12 also noted “[F]ederal law begins by placing the obligation to identify suspicious orders and to conduct due diligence on defendants. So it is **defendants** who should be able to produce: (1) a chart of every suspicious order they identified, and whether due diligence subsequently “cleared” the suspicious order; and (2) the algorithms, policies, methods, and rules used to determine initially whether an order was suspicious (the SOMS), as well as the actual efforts undertaken to assess whether a suspicious order was legitimate.” *See* DR-12 at n.9 (emphasis original).

Walgreens’s arguments regarding DR-12 do not support Walgreens’s Motion for Summary Judgment on Causation.

## **B. The Analysis Performed by Plaintiffs' Experts Supports Plaintiffs' Claims**

As addressed in Plaintiffs' Opposition to Defendants' Daubert motion regarding Dr. McCann, which Plaintiffs incorporate by reference here, Dr. McCann's report flags transactions based on various tests for identifying suspicious orders by volume. These tests include the test endorsed by the court in *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.D.C. 2017), which the court held identified orders that were "unusual," and not "normal", and thus could not legally be shipped without sufficient due diligence.<sup>83</sup> The report also identifies transactions that would have been flagged by certain other tests based on those which defendants utilized to flag suspicious orders based on volume alone.<sup>84</sup> While Dr. McCann's report contains charts and tables which aggregate the total number of transactions that would have been flagged by the tests, as well as those that would have continued to be flagged unless sufficient due diligence was performed, the materials submitted in support of Dr. McCann's report also break out each individual transaction through which Walgreens distributed opioids into Summit and Cuyahoga counties and identifies whether each transaction would have been flagged by each one of the methodologies.<sup>85</sup>

Mr. Rafalski, a former DEA agent, opined that there was no evidence that Walgreens conducted sufficient due diligence on the orders that should have been flagged as suspicious under the *Masters* formula, and further opined that those orders should legally never have been shipped to Cuyahoga County and Summit County.<sup>86</sup> Mr. Rafalski's testimony that continued shipment of suspicious orders without due diligence supports a conclusion of diversion is based in part on the DEA Diversion Investigator's Manual, which states that if a pharmacy places orders of unusual size,

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<sup>83</sup> See PD4 – Rafalski/McCann.

<sup>84</sup> See Rafalski Rep., Dkt. # 2000-22 at 40-41.

<sup>85</sup> See Exh. 61, "Walgreen" Spreadsheet, produced as part of Appendix 10 Chain Distributor Transactions with Flag[s] dataset on March 25, 2019 in support of Dr. McCann's Expert Report.

<sup>86</sup> See Rafalski Rep., Dkt. # 2000-22 at 474-475.

the order “should be viewed as suspicious,” and that “activity, over extended periods of time, would lead a reasonable person to believe that controlled substances possibly are being diverted,” as set out in the Rafalski Report.<sup>87</sup> Contrary to Walgreens’s assertion, Mr. Rafalski’s opinion that Walgreens’s shipment of suspicious orders without proper due diligence led to diversion is also supported by the DEA’s 30(b)(6) testimony that (a) once a suspicious order is flagged, all future sales should be suspended until diversion can be ruled out, (b) shipping a suspicious order without due diligence is a per se violation of federal law under the CSA, (c) shipping controlled substances in violation of the CSA is illegal, (d) diversion is foreseeable if registrants fail to comply with federal law; (e) failure to comply with federal law enables more diversion; (f) diversion is detrimental to public health and safety; and (g) the more pills unlawfully entering the market results in more diversion.<sup>88</sup>

Dr. Egilman’s opinion that Walgreens’s CSA violations related to its Jupiter, Florida DC extended beyond Florida and impacted Ohio is, in fact, supported by Walgreens’s own documents, as shown above.<sup>89</sup> *See* Statement of Facts.

Though not addressed in Walgreens’s Motion, Plaintiffs’ expert David Cutler has additionally linked excess supply of opioids to diversion and opioid-related deaths. Cutler opines that Defendants’, including Walgreens’s, failure to control the supply chain and their “deliberate efforts to evade restriction on opioid distribution” was a contributing factor to the opioid epidemic.<sup>90</sup>

Contrary to Walgreens’s assertions, Plaintiffs’ experts have provided ample support to find that Walgreens’s breaches of its CSA duties caused the harms claimed here.

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<sup>87</sup> *See* Rafalski Rep., Dkt. # 2000-22 at 15 (quoting DEA Diversion Investigator’s Manual).

<sup>88</sup> *See* Thomas Prevoznik Dep. (04/18/19), Dkt. # 1969-13 at 628-629; 632-633; 638-647; 770-771.

<sup>89</sup> Plaintiffs further adopt and incorporate in full, here, the arguments set out in Plaintiffs’ Oppositions to the Defendants Daubert Motions filed with respect to Dr. McCann and Mr. Rafalski (PD4), Dr. Egilman (PD12), Ms. Keller (PD5), and Mr. Whitelaw (PD6).

<sup>90</sup> Cutler Rep., Dkt # 2000-4 at 15 ¶ 29.

**CONCLUSION**

For the foregoing reasons and those in Plaintiffs' Consolidated Memorandum in Opposition to the Defendants' Motions for Summary Judgment on Causation Walgreens's motion for summary judgment should be denied.

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Respectfully submitted,

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